PROCEDURAL SEDATION IN CHILDREN UNDERGOING DIAGNOSTIC AND THERAPEUTIC PROCEDURES OUTSIDE THE OPERATING ROOM IN A TERTIARY CARE CENTRE - A CLINICAL AUDIT

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF **M.D. BRANCH- X (ANESTHESIOLOGY)** EXAMINATION OF **THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, CHENNAI** TO BE HELD IN **MARCH, 2007**

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ACKNOWLEDGEMENT

I express my profound gratitude to **Dr. Rebecca Jacob**, Professor, Department of Anesthesia, Christian Medical College, Vellore for her valuable guidance and constant encouragement throughout the course of the study.

I am thankful to **Dr. Manickam Ponniah**, Professor and Head, Department of Anesthesia, Christian Medical College, Vellore for the remarkable strength and support he offered.

I am extremely grateful to all my seniors and colleagues of the Department of Anesthesia for the cooperation they extended during the course of the study. I am duty bound to thank the faculty of the Departments of Hematology, Child health, Pediatric Surgery, Radiology, Gastroenterology, Neurology and ENT for the cooperation rendered.

I express my deep appreciation and thanks to **Dr. Prathap Tharyan**, Professor, Department of Psychiatry for his help in statistical analysis.

CERTIFICATE

This is to certify that "**THE CLINICAL AUDIT ON PROCEDURAL SEDATION IN CHILDREN UNDERGOING DIAGNOSTIC AND THERAPEUTIC PROCEDURES OUTSIDE THE OPERATING ROOM IN A TERTIARY CARE CENTER**" is a bonafide work of **DR.K.ILAMURUGU** for the **MD BRANCH X (ANESTHESIOLOGY)** examination of the TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI to be held in March, 2007

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INTRODUCTION

Sedation and analgesia is frequently administered to pediatric patients for procedures done outside the operating room. It is poorly understood that procedures done outside the operating room require the same attention to anxiolysis, analgesia, sedation and safety guidelines as procedures performed in the operating room. To this end we require appropriate definitions, goals, guidelines, monitoring and adequately trained personnel[1].

Nonpainful procedures like magnetic resonance imaging (MRI), computed tomography (CT scan), electroencephalography (EEG) and electromyography (EMG) require immobility but no analgesia. Procedures like radiotherapy also require an absolutely immobile patient. Painful procedures like bone marrow aspiration, lumbar puncture, repair of minor surgical wounds, and insertion of arterial and venous catheters, burns dressing changes, fracture reduction, endoscopy and bronchoscopy require deep sedation or general anesthesia.

The fear of entering a closed space for imaging studies remains considerably high. This is especially true in young children and the mentally handicapped. The whole issue is compounded by parental anxiety, seperation from parents and pain or anticipation of pain during the procedure. Procedures like bronchoscopy, endoscopy and central line placement which were previously done in operating rooms (OR) are now being increasingly done outside the OR partly due to time constraints, partly in an effort to decrease cost and partly due to fear of the complications of sedation.

Due to these factors, children are often subjected to sedation by unskilled personnel with no training in resuscitation. In other cases children who would have benefited by sedation are being denied sedation and are left with long term psychological scars.

In an effort to identify areas of sedation and monitor sedation practices we decided to

audit all children undergoing diagnostic or therapeutic procedures in our tertiary care institution, for a period of one month, after meeting the personnel of departments dealing with these children discussing the purpose of this audit and checking on equipment and personnel training available.

AIMS AND OBJECTIVES

1) To audit the existing practice of procedural sedation in children in our tertiary care centre.
2) To compare the existing practice with the international guidelines thereby analyzing the efficacy of the existing practice.
3) To recommend changes in the existing practice so as to improve patient safety during procedural sedation.

LITERATURE REVIEW

The literature has been reviewed under the following headings.

- Clinical audit
- Procedural sedation
    - definition of levels of sedation
    - history of procedural sedation
    - guidelines for procedural sedation
    - current sedation strategies
    - risks and complications of sedation

CLINICAL AUDIT

Definition

Audit is the process used by health professionals to assess, evaluate and improve care of patients in a systematic way in order to enhance their health and quality of life[2]. Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery. *This definition is endorsed by the National Institute for Clinical Excellence*[3].

Is there a difference between auditing and research? Yes!

Research	**Audit**
Discovers the right thing to do	Determines whether the right thing is being done
A series of 'one-off' projects	A cyclical series of reviews
Collects complex data	Collects routine data
Experiment rigorously defined	Review of what clinicians actually do
Often possible to generalize the findings	Not possible to generalize from the findings

Why audit?

- It is compulsory for Summative Assessment.
- It improves quality of care as both an outcome and by the process of performing the audit.
- It is an aid to continuing medical education.
- There is a sense of personal and professional achievement. It may lead to a publication and can improve a CV.

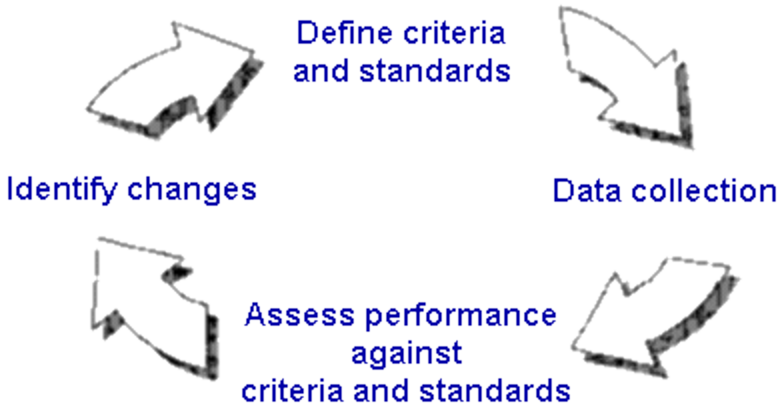
The educational benefits from audit

- Audit allows a critical review of current information (keeping up to date).
- Audit highlights the need for specific knowledge/information, the acquisition of new skills and the development of existing ones.
- Audit improves communication skills and enables attitudes to be modified when working with other members of the Primary Care Team.
- Audit enables 'self evaluation'.
- Audit promotes learning by answering the following questions:

- What am I doing?
- How am I doing it?
- Why am I doing it in that way?
- Can I do it better or differently?

How to carry out an Audit

The Audit cycle



The main features of the audit cycle can be analyzed to a greater depth.

1. **Identify the need for change .**this may come from personal experience. A problem may be identified from every day practice and following this there is a feeling that something could

or should have been done better. Problems can be identified in 3 basic areas of practice

Structure: This refers to the input of care such as manpower, premises and facilities. Eg. 'Are the numbers of emergency appointments enough to cope with demand?'

Process: This refers to the provision of care (looking at what is done and how it is done) Eg. 'Are all patients on ACEI having urea & electrolytes checked?'

Outcome*:* This refers to the result of clinical intervention. However in many clinical specialties outcome may be difficult to discern and in these cases these may be more useful to use process or even structure as a surrogate outcome measure (Eg in stroke audit the presence of a stroke audit and team as been used as a measure on the assumption that this will improve outcome[4])

2. Setting criteria and standards

This is where one can say what should be happening.

A *Criterion* is an item of care or some aspect of care that can be used to assess quality. The criterion is written as a statement. Below are three criteria one relating to an audit in structure, one an audit in process and one an audit in outcome.

- All patients requesting an urgent appointment will be seen that day.
- All patients with epilepsy should be seen at least once a year.
- All patients on Warfarin should have their INR within the recommended limits.

Criteria can be defined from recent medical literature, and the best experience of clinical practice these are called 'Normative criteria'.

To make the criteria (statement) useful the Standard needs to be defined. A Standard describes the level of care to be achieved for any particular criteria. Eg. A standard may state: 98% of patients requesting urgent appointments will be seen the same day. 90% of patients with epilepsy should be seen at least once a year. 100% of patients on warfarin will have their INR within the recommended limits.

Standards must be set. The level of standard can often be controversial. There are basically 3 options:

A minimum standard. This describes the lowest acceptable standard of performance. Minimum standards are often used to distinguish between acceptable and unacceptable practice.

An *ideal standard* describes the care it should be possible to give under ideal conditions, with no constraints. Such a standard by definition cannot usually be attained.

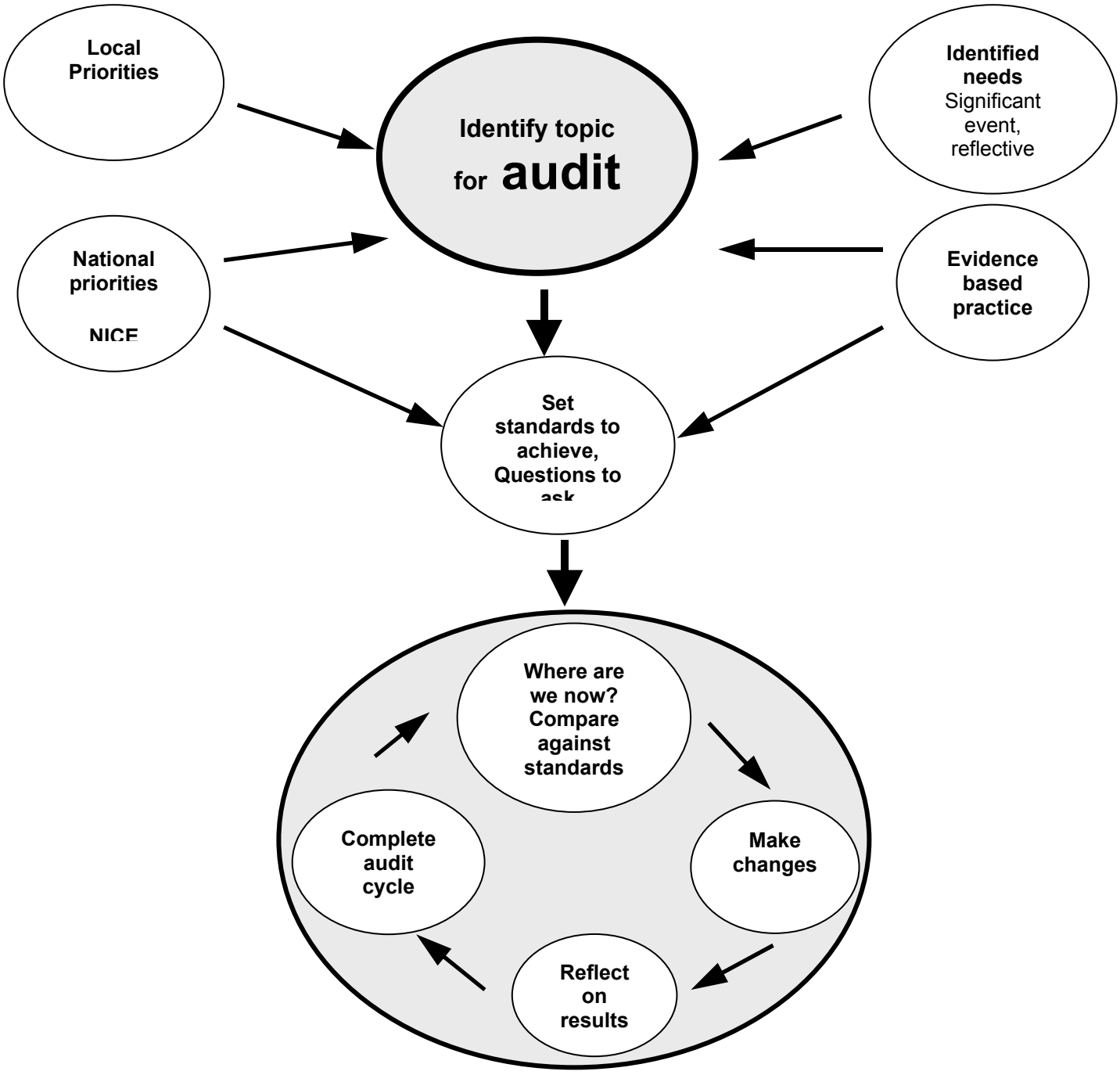
An *optimum standard* lies between the minimum and the idea. Setting an optimum standard requires judgment discussion and consensus with other members of the primary care team. Optimum standards represent the standard of care most likely to be achieved under normal conditions of practice.

3. **Collecting data on performance**. Identify what data needs to be collected, how and in what form it needs to be collected and who is going to do it. Remember only to collect what information that is absolutely essential.

4. **Assess performance against criteria and standards**. With the information collected, analysis is possible, and identification of any area of care below the predetermined standard of the criteria can be made. The results can then be used to develop an action plan i.e. what needs to be done, how it needs to be done, who is going to do it and when it is going to be done.

5. Identify the need for change. The audit cycle is now complete, but without re-evaluating the practice it is impossible to see if recommendations have been implemented and the level of care improved. In many instances process improvement alone may have to be used as a

surrogate measure for outcome improvement particularly in those areas where the projected outcome measurements are either small or of long duration (Eg improvement in thrombolysis times should improve mortality from myocardial infarction[5]).


Local Priorities
Identify topic for audit
Identified needs Significant event, reflective
National priorities
NICE
Evidence based practice
Set standards to achieve, Questions to ask
Where are we now? Compare against standards
Make changes
Reflect on results
Complete audit cycle

PROCEDURAL SEDATION

DEFINITION

Sedation is a process in continuum[6]. It ranges from minimal sedation, where the child responds normally to verbal commands, to general anesthesia, where the child is totally unresponsive to any stimulus. While demarcating the various levels of sedation is very important to recognize transition from one level of sedation to the next higher level as it requires a corresponding escalation of monitoring and expertise for managing complications. Four levels of sedation have been defined by the JCAHO (Joint Commission on Accreditation of Health Organizations) on Recommendations made by the American Society of Anesthesiology[7, 8].

Minimal sedation (anxiolysis)[6,7]: A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. This state is rarely adequate for completion of diagnostic or therapeutic procedures in children.

Moderate sedation/analgesia[6,7]: A drug- induced depression of consciousness during which patients respond purposefully to verbal; commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. This level of sedation was referred to as ‘conscious sedation” in the past[9,10]. However, the old terminology is confusing and inaccurate and is no longer used.

Deep sedation/analgesia[6,7]: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal is not considered a purposeful response. The ability to independently

maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Anesthesia[6,7]: General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

HISTORY OF PROCEDURAL SEDATION IN CHILDREN

In the 40th Rovenstine lecture[11], Burton and Epstein describe how various specialties contributed to the now accepted guidelines on pediatric sedation and analgesia. It was the dentists who first strove to strike a balance between minimizing fear and anxiety and maximizing safety[12] and in 1972 brought out the "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry"[13]. In spite of this a number of deaths were reported in dentistry. In 1985, the Committee of Dugs section on anesthesiology, American Academy of Pediatrics (AAP) in conjunction with the American Academy of Pediatric Dentistry, published guidelines for the elective use of conscious sedation, deep sedation and general anesthesia in pediatric patients[14]. The document defined the 3 states as well as the requirements for patient selection, personnel, monitoring facilities, equipment and recovery care. The definition of conscious sedation[9] includes the patient's ability to maintain a patent airway which ought to be retained independently and continuously. Also, the drugs and techniques used should carry a

margin of safety wide enough to render unintended loss of consciousness unlikely.

In 1992, the AAP published a revision of the 1985 guidelines where they noted that regardless of the intended level of sedation or route of administration, the sedation of a patient represents a continuum and a patient may move easily from light level of sedation to obtundation. The practitioner should be therefore prepared to increase the level of vigilance correspondingly. A pulsoximeter was recommended in all cases. Endoscopists were also beginning to document the risk of hypoxemia in their environment[15].

Meanwhile, in the 1980s the ASA and the JCAHO (who were also concerned by the deaths occurring outside the operating room when potent sedatives and narcotics were administered) brought out the standards for surgical and anesthesia services. The standards required that patients with the same health status receive a comparable level of quality of surgery and anesthesia care throughout the hospital. This was intended to promote safety and uniformity in the quality of care. This applied to all the specialties including endoscopy where there could be a dangerous loss of protective reflexes during scopy.

GUIDELINES FOR PROCEDURAL SEDATION

Overtime, the ASA derived guidelines from science based analysis of the literature, expert opinion and perspective of health care providers. The guidelines were drawn up by the ASA task force on sedation and analgesia. Gross and Epstein in an article enunciated several highly relevant comments[11]:

1) Among the more challenging problems facing the task force is one of terminology. Although the term conscious sedation is used frequently, it is

poorly defined, spanning the gamut from modest preprocedure sedation to minimal responsiveness during painful stimulation. Therefore… the task force concluded sedation and analgesia more accurately described the condition for which the guidelines are intended.

2) The task force intended to address scientifically whether or not the use of advanced monitoring techniques (*e.g.*, pulsoximetry, exhaled carbon dioxide detection) reduced the risk of adverse outcome.

Further recommendations include:

GOALS FOR PROCEDURAL SEDATION[6,7]

An ideal pediatric procedural sedation plan attempts to achieve the following goals

1. Allay fear and anxiety in both the child and the parents.
2. Obtain the cooperation of the child
3. Achieve immobilization of the child to the degree needed for the procedure
4. Induce unawareness and amnesia
5. Reduce discomfort and pain associated with procedure
6. Keep the child safe during and after the procedure
7. Minimize/eliminate the residual effects of sedation after the procedure is over.

The sedation plan should be modified depending on the psychological maturity of the child to achieve the set goals.

FACILITIES AND EQUIPMENT[6,7]

The appropriate equipment necessary to manage emergency situations arising from

sedation must be immediately available. A protocol for back up emergency services shall be clearly identified. The available onsite equipment should include

*positive pressure oxygen delivery system

*suction devices

*blood pressure measuring equipment

*emergency cart with age and size appropriate equipment and drugs

*defibrillator with pediatric size paddles

SKILLS AND TRAINING OF THE PERSONNEL[6,7]

The Task Force appointed by the ASA recommends the presence of two persons during sedation, one to monitor the patient during the procedure and the other to perform the procedure. During moderate sedation the person monitoring the patient can have minor, interruptible tasks but during deep sedation, this individual should have no other responsibilities. The personnel who provide sedation should have proper training and skills to assure patient safety. The individual responsible for the patient during sedation should have a good knowledge of the pharmacology of drugs being used. At least one individual on site should have skills in Basic Life Support. It is strongly recommended that an individual with Advanced Life Support skills be immediately available (within 5 minutes) for moderate sedation and within the procedure room for deep sedation.

Recently the JCAHO has introduced the concept of "rescue"[16]; that is practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than intended initially. Thus individuals, administering moderate sedation and analgesia should be able to manage children who enter a state of deep sedation, whereas those administering deep sedation should be able to manage patients who enter a state

of general anesthesia[16].

PREPROCEDURAL EVALUATION[6,7]

Appropriate patient selection is essential for ensuring safe and effective sedation. Any child undergoing any level of sedation should be evaluated before administration of sedating and anesthetizing medications. a focused presedation evaluation should include *history of*

1. Any major medical illness
2. Previous history of surgery, sedation or general anesthesia
3. Current medication and drug allergy
4. History of snoring, sleep apnea, mouth breathing and hypoventilation
5. Last oral intake

Physical examination

1. Weight
2. Vital signs: heart rate, respiratory rate, oxygen saturation, blood pressure and temperature
3. Auscultation of heart and lungs
4. Airway assessment, focusing on facial dysmorphism, retrognathia, micrognathia, trismus, macroglossia, loose teeth, dental appliances, tonsillar hypertrophy, visibility of the uvula, short neck, tracheal deviation and obesity.

The presedation evaluation should be done immediately before the procedure or if previously done should be reconfirmed prior to the procedure. ASA physical status classification is done on the child based on the presedation evaluation. A child classified as class IV or higher should be referred to a pediatric anesthesiologist. Consulting a pediatric anesthesiologist may be useful in children in class III.

PREPROCEDURAL FASTING[6,7]

For nonemergent procedures, the ASA fasting guidelines are followed. In cases of emergency, like bronchoscopy or CT scan done for trauma, the risk versus benefit ratio must be assessed and communicated to the family. Available options in such instances will include delaying the procedure, administering lighter level of sedation, if appropriate, or administering general anesthesia after securing the airway by rapid sequence induction and intubation

ASA preprocedure fasting guidelines[17]

Type of food	Fasting period
Clear liquids	2 h
Breast milk	4 h
Light solids	6 h

INFORMED CONSENT[6,7]

A sedation plan is drafted taking into consideration the specific needs for a particular child and the procedure planned. The various options, risks and alternatives should be discussed with the parents/guardians of the child and informed consent should be obtained and documented in the patient record.

MONITORING DURING SEDATION[6,7]

Baseline vital signs should be documented on a sedation flow sheet. The flow sheet should be uniform throughout the hospital for ease of use and referencing. The name, route, time of administration and dosage of all drugs administered must be recorded. Continuous pulsoximetry with an audible and visual signal is mandatory in all cases and has been shown to decrease the likelihood of adverse outcome. The time based sedation flow sheet must contain intermittent recording of heart rate, oxygen saturation, respiratory rate and blood pressure. The

recommended time interval for recording data is very 15 minutes for mild sedation and every 5 minutes for moderate and deep sedation. Ideally, vital signs should be recorded (1) at the beginning of the procedure, (2) after administration of the sedative agent, (3) at regular intervals during the procedure, (4) during initial recovery and (5) just before the patient is discharged.

POSTSEDATION CARE[6,7]

Pediatric patients receiving sedation are at a significant risk for developing airway related complications after the procedure is over. The delayed absorption of orally or rectally administered drug, slow metabolism by infants, absence of stimulus and reduced vigilance after the procedure may all contribute to this high incidence of complications.

The child must recover in a special recovery area equipped with the capacity to deliver more than 90% oxygen and adequate suction and monitoring devices.

This area should also have pulsoximeter to monitor the oxygen saturation and the heart rate every 5 minutes if the child is deeply sedated. Recommended discharge criteria include

1. Stable cardiovascular function and satisfactory airway patency
2. Child is easily aroused and protective reflexes are intact.
3. Child can speak, sit or walk (if appropriate for age)
4. Presedation level of consciousness
5. Adequate hydration

CURRENT SEDATION STRATEGIES

Sedation is not a primary therapy but rather a treatment of procedural side effects such as pain, anxiety and dangerous movement. Inability to handle the side effect may mean the

avoidance of sedative drugs, as it is known that no child may die of their pain or stress. However, pain, anxiety, psychological trauma to the patient and the parents, as well as loss of valuable time and less than optimal results will be the price to pay for not sedating them.

A sedation plan analyzing the requirements for analgesia, anxiolytics or both is necessary for each patient and will vary depending on the procedure and the anxiety of the patient and family. Psychological techniques (cuddling, parental support, warming blankets, gentle reassuring voice and hypnosis) are extraordinarily useful adjuncts to the sedation plan.

Many newer sedative agents have emerged. Intranasal, transmucosal and rectal routes are often helpful in children who do not have an intravenous access. Nevertheless, for deep sedation, an intravenous access should be obtained before the administration of sedation. Many drugs can be used to achieve the same end point. Some of the commonly used drugs are described.

Chloral hydrate: Chloral hydrate is one of the most widely used sedative agents in children. It provides effective sedation but not analgesia[18]. Although it is considered safe, the drug can often produce deep level of sedation and has been associated with adverse outcomes such as airway obstruction, respiratory depression and death[19,20,21]. The active metabolite, tricholroethanol, has a half life of 10 hrs in toddlers, 18 hrs in term infant and 40 hrs in preterm infants. It can be given orally or rectally. Its onset of action is 30-60 minutes and usual duration is 1 hr. the unpredictable onset and active metabolites dictate that this drug is given only in areas with facilities for resuscitation (AAP guidelines).

Benzodiazepines: midazolam is the most commonly used drug in this class of agents. It can be administered through oral, intranasal[22], rectal, intramuscular or intravenous routes. It has potent amnesic and anxiolytic properties. It does not have any analgesic property and often needs to

be combined with topical, local or regional analgesic or systemic agents such as a narcotic or ketamine. The combination of midazolam with an opioid such as fentanyl has been popular but can cause immense respiratory depression[23,24]. Respiratory depression caused by midazolam can be reversed by using a specific antagonist, flumazenil.

Opioids: Opioids such as fentanyl are used often in conjunction with a sedative such as midazolam or propofol, to achieve analgesia for painful procedures. The fentanyl and midazolam combination is very effective in achieving rapid onset sedation and analgesia, although the risk of profound respiratory depression is high[25]. Rapid onset of action, shorter duration of effect, lack of histamine release and less cardiovascular depressant action are the advantages of fentanyl. Respiratory depression, pruritus, nausea and vomiting, hypotension and chest wall rigidity[25] on rapid intravenous administration are reported with this class of drugs. Remifentanyl[26] is an ultra-short acting opioid which is being increasingly used for procedural sedation. The incidence of respiratory depression is very high with its use. Naloxone is an effective andidote for respiratory depression induced by opioids.

Ketamine: Ketamine is a dissociative anesthetic. It provides excellent amnesia, analgesia and sedation for procedures including fracture reduction, repair of lacerations and other painful procedures[27,28,29]. It can be administered intravenously or intramuscularly. It is regarded safer than the other classes of drugs because of its less pronounced effects on respiration. However, it does produce excessive salivation and airway secretions and there is a considerable risk of aspiration or airway obstruction. It is therefore almost always used in conjunction with an antisialogogue such as atropine or gycopyrolate. The incidence of emergence dysphoria and hallucination is high with the use of ketamine. Benzodiazepines such as midazolam are used in conjunction with ketamine in an effort to decrease emergence dysphoria[29]. However, there are

recent reports suggesting that no additional benefits are gained by the concurrent use of benzodiazepines.

Propofol: Propofol has many desirable characteristics for sedation in children. They are: extremely rapid onset, substantial potency that reliably produces effective conditions for performing procedures, short recovery time (5-15min), and high satisfaction to the patient because of its antiemetic and euphoric properties. Propofol can be given in these settings with good efficacy, safety and rapid recovery[30]. The most serious side effect of propofol is respiratory depression and apnea. The incidence of respiratory depression varies from 8-30%[31] and seems to be related to the technique of administration. Propofol induced hypotension is typically transient. Although hypotension is not a problem in healthy patients, it may pose a significant risk in debilitated children. The addition of lignocaine has been shown to decrease the incidence of pain on injection of propofol. The recommended dose of lignocaine is 1 ml to every 10 ml of propofol[32].

Routes of administration:

Topical Agents Topical analgesia has substantially reduced the discomfort associated with laceration repair, intravenous cannulation, and lumbar puncture in children by providing a noninvasive means of delivering local anesthesia. The first available topical anesthetic for nonintact (lacerated) skin was a combination of tetracaine, epinephrine, and cocaine referred to as TAC[33]. Recently, this combination has been widely replaced by lidocaine, epinephrine, and tetracaine (LET)[34,35,36], which is safer, less expensive, and equally effective, and has an onset time of approximately 20 minutes.

Intact skin can be treated with sprays that numb by cooling (ethyl chloride or fluoromethane) for procedures lasting less than one minute, such as intravenous cannulation, or with a eutectic mixture of local anesthetics, or EMLA (2.5 percent lidocaine and 2.5 percent prilocaine in a cream base) to provide one to two hours of anesthesia for intravenous cannulation or lumbar puncture. The chief disadvantage of the eutectic mixture is the relatively long time to peak effect (60 minutes), a delay that cannot be circumvented, since 30 to 40 minutes produces inadequate analgesia. Recent reports describe success in delivering lidocaine transdermally by electrical current (iontophoresis). This noninvasive technique shows promise for reducing the discomfort of intravenous cannulation[37,38,39].

Transmucosal Agents The use of fentanyl lozenges initially appeared promising as a method of delivering opioids by a noninvasive route through the oral mucosa, but unacceptably high rates of emesis (31 to 45 percent) have limited the popularity of this method.[40]

Systemic Agents

The short-acting opioid fentanyl is preferred to the traditional long-acting meperidine and morphine for procedural analgesia because its action has faster onset and shorter duration and involves no histamine release[41]. Concomitant administration of an antiemetic is not usually required with fentanyl. This opioid causes pruritus in the nasal area that may interfere with procedures. Morphine and meperidine remain the preferred agents for analgesia of longer duration. The effects of opioids can be reversed with the antagonist naloxone.

RISKS AND COMPLICATIONS ASSOCIATED WITH PROCEDURAL SEDATAION

Provision of safe sedation and analgesia for procedures on children requires skill and organization of resources to prevent severe negative patient outcomes. True sedation disaster is rare and the number of such cases reported in the literature is too small to interpret the safety of any of the methods of sedation. Fatalities reported, may only be the tip of the iceberg as studies of rare events require thousands of cases[42]. Unfortunately, there are no large, multicentre trials to evaluate the safety of procedural sedation. It is for this reason that common events like desaturation,airway obstruction, apnea and other cardio respiratory events are used as surrogate markers for the more serious but rare events such as death and permanent neurological injury.

Definition of terms[43]

Adverse events are classified according to acuity and placed in different categories.

Category A: This category encompasses the most serious events which include the need for resuscitation, cardiovascular complications, decrease in oxygen saturation, aspiration, allergic reaction and the use of reversal agent.

Category B: prolonged sedation (greater than 3 hours recovery time), vomiting, unplanned admission and paradoxical reaction.

Category C: failed sedation awakens before procedure and greater than 3 attempts for securing an intravenous access.

Failed sedation: inadequate sedation subsequent to receiving the maximum allowable dosages ass per the sedation protocol or inability to complete the planned procedure secondary to unacceptable motion artifact

Prolonged sedation: inability to meet discharge criteria 3 hours following administration of the sedative or failure to return to baseline mental and behavioral status within 24 hours of

receiving sedation.

Paradoxical reaction: a rage, irritability or agitation that was not present prior to sedation.

"**Adverse sedation events in pediatrics**: a critical incident analysis of contributing factors" published in Pediatrics in 2000[44] considered only four outcome measures in the total of 118 case reports, namely; death, permanent neurological injury, prolonged hospitalization without injury, and no harm. All the 118 cases were independently examined by four investigators to find the probable cause of adverse events. Subsequently all four investigators reached a consensus on the contributory causes, which are as follows.

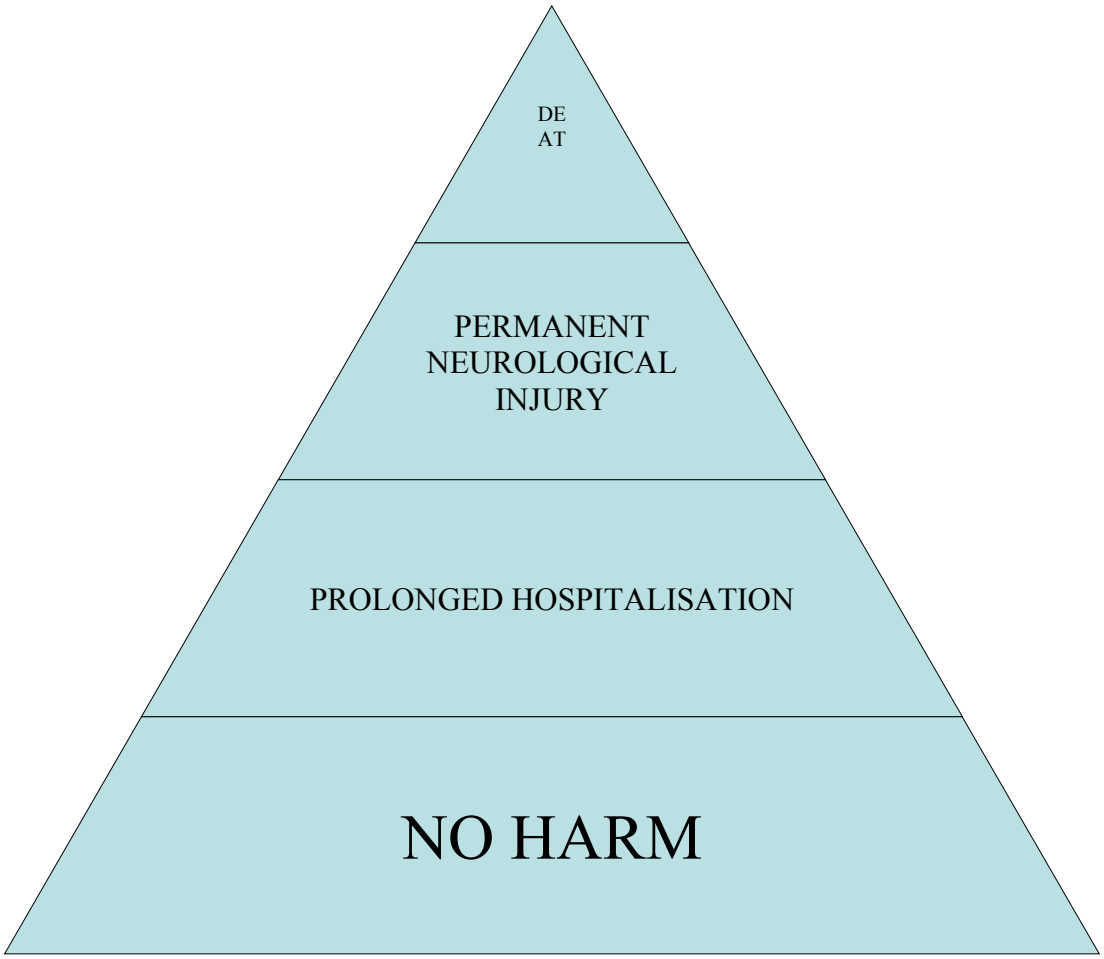
1. An important association with outcome was venue. Adverse events that occurred in a non-hospital based venue were far more likely to result in severe neurological injury or death than were adverse events that occurred in a hospital although patients cared for in non-hospital venues were generally older and healthier than those sedated in hospital based facilities.
2. Inadequate monitoring, especially failure to use or respond to pulsoximetry, was rated as a major factor contributing to poor outcome.
3. Other determinants of adverse outcomes were: errors in managing complications (failure to rescue), inadequate preprocedural evaluation, medication errors, inadequate recovery procedures and the lack of an independent observer.

Charles Cote et al did an analysis on medications used for sedation and how they contribute to the occurrence of adverse events[45]. They found that children have suffered adverse sedation-related outcomes with a variety of medications which do not seem to be related to drug category or route of drug administration. Even chloral hydrate administered well within the recommended maximal dose limits can cause serious morbidity and mortality. Chloral hydrate

should be considered a long-acting drug, capable of severe respiratory depression and/or airway obstruction. Medications with long plasma half-lives (chloral hydrate, promazine, promethazine, chlorpromazine, and pentobarbital) accounted for most of the deaths/injuries that occurred in automobiles or at home after a procedure. Prescription and transcription errors occur with sufficient frequency as to underscore the importance of a systematic approach to all patients who receive sedative medications, e.g., setting mg/kg dose limits, using standardized dosing regimens, and double-checking all doses before their administration. Even standard and acceptable doses of drugs can cause significant morbidity and mortality if the patient is not properly observed. They suggested that the definitions for the various levels of sedation should be unified among specialists.

Conclusions derived from these studies[44,45] include

- all areas using sedation have reported adverse events
- most complications from sedation were avoidable
- All classes of drugs (sedatives, barbiturates, benzodiazepines and narcotics) have been associated with problems even when administered in recommended doses.
- Adverse events involved multiple drugs (especially three or more sedating medications), drug errors or overdose, inadequate medical evaluation, inadequate monitoring, inadequate practitioner skills and premature discharge.
- Respiratory depression, airway obstruction, desaturation and apnea are the most frequently encountered initial adverse events and cardiac arrests and neurological damage occur as secondary events.
- Children between 1 and 6 years of age at greatest risk. Most had no severe underlying disease.


DE
AT
PERMANENT
NEUROLOGICAL
INJURY
PROLONGED HOSPITALISATION
NO HARM

MATERIALS AND METHODS

Phase I: sedation practices are not uniform across the hospital .Reports of morbidity led us to look at the problems in the existing practice and to **identify the need for change**

Defining criteria and standards: We looked at and accepted the JCAHO and ASA guidelines as the standard against which we would compare and or assess modes of sedation /analgesia in our centre.

Phase II: **Identification of areas** where procedural sedation is given: the next step in carrying out the audit is the identification of areas where sedation and analgesia are practiced. We chose seven departments in the hospital who were sedating children on a regular basis for diagnostic and therapeutic procedures. These included departments of child health, pediatric surgery, hematology, neurology, otorhinolaryngology, radiology and gastroenterology. The anesthetists were involved directly in the MRI suite, CT scan area, sonology suite and in the endoscopy room. In the other areas, nonanesthesiologists were involved in sedating children for procedures.

Phase III: **Information and permission:** Prior to starting the data collection, we contacted the departments we had identified in phase II and presented the need to do this audit, at their clinical meetings. This was done with a short power point presentation as well as the proforma,

for their perusal and comments. Their input was co-opted into our next phase of "data collection".

Phase IV: Data collection: This phase was planned for a period of one month simultaneously in all the areas. Two separate data collection sheets were used. The first proforma helped document the ***structure*** of the sedating area. It collected general details about the sedation.

1. Facilities and equipment available in the area.
2. Personnel present during sedation and their training in resuscitation
3. Sedation protocol followed.
4. Documentation
5. Discharge criteria or protocol

These details were collected by the investigator with the permission of the concerned personnel

The second proforma was individualized to each patient (***process***). This had the following details

1. Patient information (name, age sex, hospital number, diagnosis and current medications)
2. Details of preprocedural evaluation (history and examination findings)
3. Drugs used on the patient, dosage route and time of administration.
4. Details of the monitoring don eon the patient
5. Postprocedural complications if any
6. The criteria met at discharge

These details were filled up in the sheet by the physician or surgeon doing the procedure.

Phase V: Assessing performance (outcome) against standards. To compare the data

collected with the international standards

Phase VI: Identification of the changes needed. After comparing the existing practice with the JCAHO and ASA guidelines, certain recommendations which would improve patient safety will be drafted.

Phase VII: Feedback to the concerned departments. The data collected and the drafted recommendations were then presented to each of the seven departments as a power point presentation.

STATISTICAL METHODS

The study is a clinical audit done for a period of one month (November 2005). We included all children who underwent procedures under sedation in the identified areas as our study group. We had a total of 252 cases in the study period.

After data collection, ***descriptive analysis*** of the data was done to compute the ***frequency*** and ***percentage*** of occurrence of deficiencies and complications; a deficiency being the absence or nonavailabilty of a facility or requirement (appendix III & IV).

As the total number of cases is less (n=252), it is very difficult to calculate the statistical significance, but it has got enormous clinical significance which will be dealt with in detail under “discussion”.

AREA	NO. OF CASES
1.HEMATOLOGY OPD AND WARDS	16
2.GASTROENTEROSCOPY SUITE	19
3.EEG ROOM	114
4.AUDIOLOGY ROOM	16
5.RADIOLOGY SUITE	32
6. CHILD HEALTH OPD AND WARDS	41
7. PEDIATRIC SURGERY OPD AND WARDS	14
TOTAL	252

Table1 – Areas where sedation is administered to children with the number of cases in each area.

AREA	PROCEDURE	NO. OF CASES	
		OPD	WARD
1.HEMATOLOGY OPD AND WARDS	BONE MARROW BIOPSY	5	3
	LUMBAR PUNCTURE	3	2
	BM BIOPSY AND LP	2	1
2.GASTROENTEROSCOPY SUITE	GASTROSCOPY AND OR COLONOSCOPY	18	
3.EEG ROOM	EEG	96	
	TELEMETRY	18	
4.AUDIOLOGY ROOM	BAER	15	
	OAE	1	

5.RADIOLOGY SUITE	MRI	25	
	CT SCAN	5	
	USG GUIDED RENAL BIOPSY	3	
6. CHILD HEALTH OPD AND WARDS		OPD	WARDS
	BONE MARROW BIOPSY	4	2
	LUMBAR PUNCTURE	8	1
	INTRATHECAL INJECTION	18	
	LP & IT INJECTION	3	
	PICC	3	
	ECHO		1
	ULTRASOUND		1
7. PEDIATRIC SURGERY OPD AND WARDS	CIRCUMCISION	4	
	LYMPH NODE BIOPSY	4	
	HERNIOTOMY	2	
	DEBRIDEMENT	1	
	EXCISION BIOPSY	2	
	ANOPLASTY	1	

Table 2 - The number of procedures done in each of the seven areas.

	With sedation	Without sedation
Lumbar punctures done in child health OPD in November 2005	30	38

Table 2 a – Total number of lumbar punctures done in child health OPD

RESULTS

In the month of November 2005, the total number of procedures done under sedation in children in all the seven areas was 252 (Table1). The EEG lab did the maximum number of cases. The number of individual procedures done in each of these areas is shown in table 2. The results were analyzed in two sections as were the materials and methods, i.e. structure and process.

The collection of data was done under two headings

a) The *structure of the sedating area* i.e.; facilities and equipment available as well as the protocol followed to sedate children in all seven areas and

b) The *data pertaining to the individual patient(process)* .This was done by the physician or the nursing staff or the paramedical worker present in the area during the procedure.

Structure

(Tables 1-6; frequencies for the same are found in Appendix III)

The *most common procedure* done in the hematology and child health outpatient departments and the wards is lumbar puncture. Lumbar puncture is done as a diagnostic procedure in hematology wards and OPD but in the child health OPD it is also used as a therapeutic procedure for intrathecal injection of methotrexate in patients with hematological malignancies.

	HEMATOLOGY		GE SCOPY	EEG	AUDIOLOGY	RADIOLOGY	CHILD HEALTH		PEDIATRIC SURGERY	
FACILITIES AND EQUIPMENT	OPD	WARD					OPD	WARD	OPD	WARD
Oxygen delivery system	+	+	+	--	--	+	+	+	+	+
Suction devices	+	+	+	--	--	+	+	+	+	+
Pulsoximeter	+	+	+	--	--	+	+	+	+	+
Emergency cart with age and size appropriate equipment	+	+	+	--	--	+	+	+	+	+
PERSONNEL 1.First person training in BLS	+		+	--	--	+	+	+	+	+
First person training in PALS	--		+/-	--	--	+/-	+	+	--	--
2.Second person training in BLS	+/once attended		+	--	--	+	once attended		once attended	
3.Anesthetist involved	NO		YES	NO	NO	YES	NO		NO	

TABLE 4 - “Structure” of the sedating area
+ PRESENT
-- ABSENT

In the child health OPD, a total of 30 cases of diagnostic and therapeutic lumbar punctures were done with sedation (Table 2). But in the study period, an additional number of 38 lumbar punctures were done *without* sedation or analgesia with mere restraint only (Table 2a). Infants who could be restrained and older children who would cooperate for the procedure formed a large portion of the group who were not administered sedation or analgesia.

The *facilities* and *equipment* available for administering sedation and for resuscitating children in each of the areas is shown in the Table 3. All the areas except for EEG lab and audiology lab had age and size appropriate equipment to resuscitate a child. However, a defibrillator as recommended by JCAHO is not available in any of these areas.

Personnel: Anesthetists trained in PALS are available in the gastroscopy and the MRI suite. The doctors administering sedation in hematology and pediatric surgery OPD and wards are trained in Basic Life Support but do not attend regular updates. They also lack advanced training in pediatric life support. The physicians administering sedation in the child health department are trained in PALS, again not subjected to regular updates.. Technicians with no training in BLS administer sedation in the EEG and audiology lab (refer Table 3).

AREA	DRUGS USED
1.HEMATOLOGY OPD AND WARDS	1.KETAMINE 2.MIDAZOLAM 3.ATROPINE
2.GASTROENTEROSCOPY SUITE	1.KETAMINE 2.PROPOFOL 3.HALOTHANE 4.NITROUS OXIDE
3.EEG ROOM	1.TRICHLORYL 2.LORGACTIL 3.DIAZEPAM
4.AUDIOLOGY ROOM	1.TRICHLORYL
5.RADIOLOGY SUITE	1.TRICHLORYL 2.KETAMINE 3.PROPOFOL 4.HALOTHANE 5.ISOFLURANE 6.NITROUS OXIDE
6. CHILD HEALTH OPD AND WARDS	1.KETAMINE 2.DIAZEPAM 3.ATROPINE
7. PEDIATRIC SURGERY OPD AND WARDS	1.KETAMINE 2.DIAZEPAM 3.ATROPINE 4.TRICHLORYL

Table 4 – Drugs used for procedural sedation in various areas

For procedures which require only sedation like electroencephalogram, MRI without contrast and audiology studies the most commonly employed drug is trichlofos (Table 4).EEG lab also administers oral diazepam and oral largactil for sedating children. Anesthetists in MRI suite administer deep sedation or general anesthesia with halothane and propofol if the procedure necessitates gadolinium injection or if the child is uncooperative.

For procedures requiring analgesia along with sedation like lumbar puncture and bone marrow biopsy, the most commonly employed drug is ketamine. Wherever ketamine is used it is being combined with an antisialogogue like atropine or glycopyrrolate and a hypnotic like diazepam and midazolam. Hematology OPD and wards use midazolam whereas child health and the pediatric surgery departments employ diazepam as the hypnotic.

Propofol is only being used by anesthetists in the gastroscopy and MRI suites. Fear of airway obstruction, apnea and respiratory depression which require advanced airway management skills restrains the nonanesthesiologists from using propofol, in spite of its rapid onset and recovery time.

PREP ROCEDURE HEALTH EVALUATION	HEMATOLOGY	GE SCOPY	EEG	AUDIOLOGY	RADIOLOGY	CHILD HEALTH	PEDIATRIC SURGERY
Age	+	+	+	+	+	+	+
Weight	+	+	--	+	+	+	+
History	+	+	--	--	+	+	+
Review of systems	+	+	--	--	+	+	+
Airway	--	+	--	--	+	--	--

examination							
Vital signs	+	+	--	--	+	+	+
Current medications	+	+	--	--	+	+	+
Starvation status	+	+	--	--	+	+	+

Table 5 – Data collection sheet I a + PRESENT --ABSENT

MONITORING	HEMATOLOGY	GE SCOPY	EEG	AUDIOLOGY	RADIOLOGY	CHILD HEALTH	PEDIATRIC SURGERY
During the procedure							
Saturation(SpO2)	Y	Y	N	N	Y	Y	Y
Respiratory rate	Y	N	N	N	Y	Y	Y
Blood pressure	Y	Y	N	N	N	Y	Y
Level of consciousness	Y	Y	N	Y	Y	Y	Y
Documentation every 5 minutes	Y	Y	N	N	Y	N	Y
Post procedure							
Saturation(SpO2)	N	Y	N	N	N	N	Y
Respiratory rate	N	N	N	N	N	N	Y
Blood pressure	N	N	N	N	N	N	Y
Level of consciousness	Y	Y	N	Y	Y	Y	Y
Documentation every 15 minutes	N	N	N	N	N	N	Y

Table 5 - Data collection sheet I b
Y – YES N - NO

Preprocedural health evaluation and fasting guidelines (Table 5-sheet Ia) for appropriate patient selection is essential for ensuring safe and effective sedation. A comprehensive health evaluation is done by all the departments except in the EEG lab and in the audiology suite. Airway examination including history of snoring and apnea is done where anesthetists employ sedation.

All other places including the audiology lab are strict in the fasting schedule. However, the technicians in the EEG lab sedate children even if they are fed within 4 hours of the procedure.

Intraprocedural monitoring of oxygen saturation and heart rate is done in all the areas except the EEG and the audiology labs (Table 5-sheet Ib). Blood pressure and the respiratory rate are rarely monitored. Even if these parameters are being monitored they are not properly documented (table 6). Some areas use flow sheet for documenting vital signs. These flow sheets are different in different departments and are then not uniform throughout the hospital. Hematology department employs a flow sheet where all the details are being entered. Anesthetists use the anesthesia record in the MRI and gastroscopy suite to record the vital signs. The department of pediatric surgery records all the sedation details on to the nurse's record.

Post procedural monitoring (Table 5 – sheet Ib). This needs to be documented every 15 minutes on to the flow sheet. Again this is not done in most of the areas except in pediatric surgery OPD and the gastroscopy suite.

POST SEDATION CARE	HEMATOLOGY	GE SCOPY	EEG	AUDIOLOGY	RADIOLOGY	CHILD HEALTH	+ PEDIATRIC SURGERY
Recovery area	--	+	--	--	--	--	+
Facilities in the recovery area							
Pulsoximeter	--	+	--	--	--	--	+
Suction devices	--	+	--	--	--	--	+
Oxygen supply	--	+	--	--	--	--	+
Discharge criteria checked	+	+	--	--	+	+	+

Table 5 - Data collection sheet I c+ PRESENT
--ABSENT

DOCUMENTATION	HEMATOLOGY	GE SCOPY	EEG	AUDIOLOGY	RADIOLOGY	CHILD HEALTH	? SURGERYPEDIATRIC
Informed consent	?	+	--	--	+	--	?
Flow sheet for sedation	+	+	--	--	+/--	--	--
Details of drugs given	+	+	--	--	+	--	+
Vital signs every 5 minutes during procedure	+	+	--	--	+/--	--	+
Vital signs every 15 minutes post procedure	?	--	--	--	--	--	+

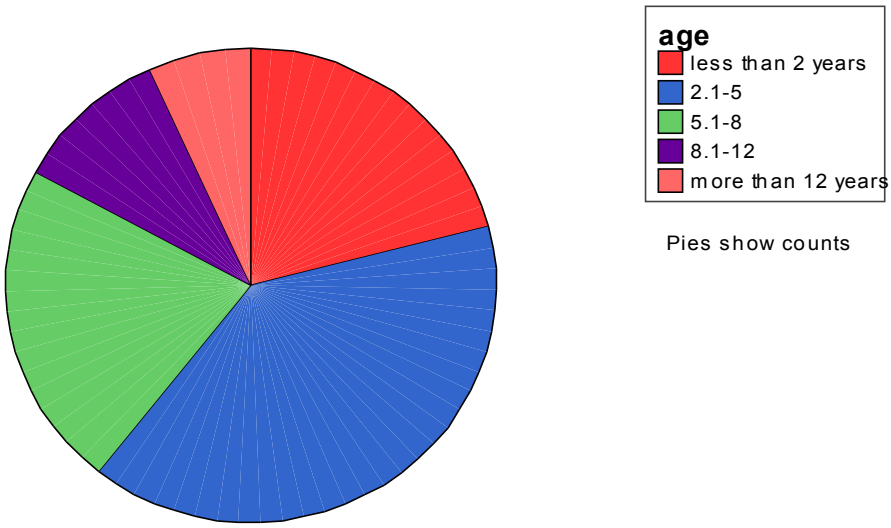
Table 6 – Documentation of sedation details

+ PRESENT --ABSENT

Process:

Individual patients were studied in different areas.

Age: Children up to 15 years of age were included under the study. The frequency of occurrence of each of these age groups is shown in the table. Children between 2-5 years formed the largest number (39.7%).



		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 2 years	53	21.0	21.0	21.0
	2.1-5	100	39.7	39.7	60.7
	5.1-8	56	22.2	22.2	82.9
	8.1-12	26	10.3	10.3	93.3
	more than 12 years	17	6.7	6.7	100.0
	Total	252	100.0	100.0	

Table 7 – Frequency distribution of age group

AREA	ADVERSE EVENT	NUMBER OF ADVERSE EVENTS	TOTAL NUMBER(n)OF CASES IN THE AREA
1.HEMATOLOGY OPD AND WARDS	CATEGORY A	2	16
	CATEGORY B	NIL	
	CATEGORY C	NIL	
2.GASTROENTEROSCOPY SUITE	CATEGORY A	1	19
	CATEGORY B	NIL	
	CATEGORY C	NIL	
3.EEG ROOM	CATEGORY A	1/ NOT MONITORED	114
	CATEGORY B	NOT MONITORED	
	CATEGORY C	NOT MONITORED	
4.AUDIOLOGY ROOM	CATEGORY A	NOT MONITORED	16
	CATEGORY B	NOT MONITORED	
	CATEGORY C	NOT MONITORED	
5.RADIOLOGY SUITE	CATEGORY A	3	32
	CATEGORY B	2	
	CATEGORY C	NIL	
6. CHILD HEALTH OPD AND WARDS	CATEGORY A	7	41
	CATEGORY B	?	
	CATEGORY C	NIL	
7. PEDIATRIC SURGERY OPD AND WARDS	CATEGORY A	3	14
	CATEGORY B	NIL	
	CATEGORY C	NIL	

Table 7 – categorical incidence of adverse effects in the study areas

CATEGORY A - cardiovascular complications, desaturation, aspiration, allergic reactions, use of a reversal agent and need for resuscitation

CATEGORY B - prolonged sedation (more than 3 hours), vomiting, unplanned admission and paradoxical reaction

CATEGORY C - failed sedation or greater than 3 attempts at securing intravenous access

The incidence of ***adverse effects*** with sedation both during and after the procedure is given in table 7 and appendix IV. The EEG and the audiology lab did not do monitoring of vital parameters on any of the children sedated in their area. The areas which lacked a recovery area did not do postprocedural monitoring. So the incidence quoted in table 7 is actually an underestimation of the existing problem. *During the procedure,* of the total of 252 children sedated in the hospital in November 2005, 153 cases (60.7%) did not have any sort of monitoring on them (this includes 114 cases from EEG lab and 16 cases from the audiology lab). *Post procedure*, of the 252 cases 171 cases (67.9%) were not monitored for complications.

Life threatening adverse events which are classified as category A events occurred in 2 of the 16 cases in hematology OPD and wards, 1 of the 19 cases in gastroscopy suite, 3 out of 33 cases in the radiology suite, 7 out of 41 cases in the child health OPD and wards and 3 out of 14 cases in the pediatric surgery OPD and ward. Though the EEG lab did not monitor the children under their custody, one life threatening event is reported from this area because the child had to be admitted in the intensive care unit for resuscitation and monitoring.

We then analyzed the frequency of occurrence with regard to the adverse effects. There were total of 11 cases of desaturation. Ten of those recorded were during the procedure and one after the procedure. But not all 252 cases were monitored. So the actual incidence could be much more than the perceived incidence.

Intra procedure desaturation:

Number of desaturation -10	Number of desaturation -10
Patients monitored – 99	Total number of patients - 252
Percentage desaturated – 9.99%	Apparent percentage of desaturation - 4%

Post procedure desaturation

Number of desaturation -1	Number of desaturation -1
Patients monitored – 81	Total number of patients - 252
Percentage desaturated – 1.25%	Apparent percentage of desaturation – 0.4%

DISCUSSION

The present audit was done in an attempt to support and improve institutional quality assurance. We hoped to analyze the data collected and then recommend changes to the present practice so as to improve outcome.

It is poorly understood that procedures done outside the operating room require the same attention to anxiolysis, analgesia, sedation and safety as procedures performed in the operating room. Sedation for procedures in children is often done by nonanesthetists outside the operating room and children are often subjected to sedation by unskilled personnel with no training in resuscitation. In our study this was seen in the EEG and audiology labs. In other cases, the care giver is afraid of complications and children who would perhaps have benefited by sedation are being denied sedation as in the child health OPD in our study. They may be left with long term psychological scars.

The necessity for change in the current policy on procedural sedation in children in our 2000 bedded tertiary care centre came from the personal experience of one of the consultants. As anesthesiologists, we encountered few children in the MRI suite of our centre who had come from the EEG lab immediately after the procedure (EEG) was over. All of these patients were deeply sedated (responding only to repetitive or painful stimulus).They were not fit for discharge from the hospital premises but had been asked to leave the EEG suite. In the cases in question, the parents of the deeply sedated children had no details as to what drug and how much of it was given to the baby. On retrospective analysis/enquiry, it was found that each patient was given one or more drugs over a period until they were perceived to be sedated enough for the procedure. The lab did not have a set protocol for procedural sedation. We also found that many other areas in the hospital

had either no protocol or some lacunae in their existing protocol. A clinical audit on the existing sedation practices in our tertiary care centre was then felt very necessary to improve patient safety. Thus we entered the first phase of an audit which was to identify the need for change.

Once this was done we needed to enunciate or define the criteria and standards for procedural sedation and analgesia in children. We looked at and accepted the JCAHO and ASA guidelines as the standard against which we would compare and/or assess modes of sedation /analgesia in our centre.

We then identified seven areas in our hospital where procedural sedation was commonly performed. These included the departments of child health, pediatric surgery, hematology, neurology, otorhinolaryngology, radiology and gastroenterology. The anesthetists were involved directly only in the MRI suite, CT scan area, sonology suite and in the endoscopy room.

We then drew up a proforma for data collection and presented this along with our concerns regarding the existing sedation practices to the faculty of the seven departments. This was done in their clinical meetings with the help of a power point presentation. After informing the concerned departments about our audit and obtaining prior permission, phase IV (data collection) was planned for a period of one month simultaneously in all the seven areas. The month chosen to do this audit was November 2005. In retrospect this was not a good month to study as the total number of patients was fewer due to the Deepawali festival.

The collection of data was done under two headings

a)The ***structure*** of the sedating area, that is, facilities and equipment available as well as the protocol followed to sedate children in all seven areas was recorded by one of the investigators and

b) The data pertaining to the individual patient ***(process)*** which was done by the physician or the nursing staff or the paramedical worker present in the area during the procedure.

Though all the concerned departments had initially agreed to participate in the audit, the willingness to participate differed from department to department (Table 8). The EEG lab where sedation was given by technical staff with no definite protocol to follow was very willing to participate and draw up protocols; whereas the child health department including the nurses considered this as an additional burden to their routine work.

The *facilities* and *equipment* available for administering sedation and for resuscitating children in each of the areas is shown in the table number 3. All the areas except for EEG lab and audiology lab had age and size appropriate equipment to resuscitate a child. However, a defibrillator was not available in any of these areas.

Personnel: the Task Force appointed by the ASA strongly recommends the presence of a person who is trained in pediatric advanced life support (PALS) when deep sedation is given. If moderate sedation is employed, a person trained in PALS should be available within 5 minutes. Anesthetists trained in PALS are available in the gastroscopy and the MRI suite. In the hematology and pediatric surgery OPD and wards, doctors administering sedation are not trained in PALS but they and their nurse assistants are trained in BLS. The physicians administering sedation in the child health department are trained in PALS. Technicians with no training in BLS administer sedation in the EEG and audiology lab. It was noticed that though many of these health care givers had BLS and PALS training at some time in their career none of them had repeated exposure to training nor were they a part of an ongoing resuscitation training program.

Informed consent: In most departments, the procedure was explained to the parents but

informed consent was taken only in the radiology and the gastroscopy suites. International guidelines state, a written informed consent is considered essential for all procedures and sedation. Parents must be provided factual, fair and comprehensive information so as to be able to understand the risks of procedural sedation prior to giving consent.

Preprocedural health evaluation for appropriate patient selection is essential for ensuring safe and effective sedation. A comprehensive health evaluation is done by all the departments except in the EEG lab and in the audiology suite, where technicians do the procedure.

The ideal pediatric sedative *drug* should maintain patient's ventilation, provide hemodynamic stability, provide patient immobility and allow easy drug titration. Ideal pediatric sedative drugs should also ensure rapid anesthetic induction and recovery while causing minimal side effects such as nausea, vomiting, dysphoria or pain. None of the drugs used by care givers in our audit met all the criteria described above.

The most commonly used drug for sedation only as seen in our audit was trichlofos and that for sedation with analgesia was ketamine. Atropine or glycopyrrolate is always combined with ketamine. To prevent hallucinations, midazolam or diazepam is being combined with ketamine. As diazepam has a longer elimination half-life, we recommend the use of midazolam to reduce the excitatory side effects of ketamine.

Propofol is often used by the anesthetists who feel they can easily control the airway. The child is street fit immediately after the procedure with little or no vomiting. However, hypotension and bradycardia are observed when propofol is used as a single drug with decrease of mean arterial pressure by 15-30% and hear rate by 17-24%. Also respiratory events make up a large proportion (5.5%) of the complication of sedation in children with propofol. we therefore recommend that propofol should only be used by anesthetists, who should carefully monitor and document

respiratory and hemodynamic events.

Largactil was being used in the EEG lab, but after phase IV of our audit and discussion with the team, it has been banned for use for procedural sedation. According to Korogh et al inadequate sedation (category C) is the most common adverse event (5-15%) resulting in failure (3-7%) of MRI procedures. We noticed a similar incidence of failure especially among children undergoing EEG studies where the procedure was abandoned or the children were given high doses or a mixture of drugs to sedate them. The failure rate may decrease if a protocol for sedation is developed.

Charles cote et al reviewed 118 case reports obtained from the database of the Food and Drug Administration (FDA) Spontaneous Reporting System from 1969 through March, 1996. 23 reports were excluded from analysis because they had inadequate data. Of the 95 cases, 51 resulted in death, 9 in permanent neurological injury, 21 had prolonged hospitalization without injury and in 14 there was no harm. On critical incident analysis of these 95 cases, some indicator of respiratory compromise was the most common presenting event in more than 80% of the cases. They also noted that the incidence of adverse events was higher when more than one sedative drug was used.

In our study, *during the procedure,* of the total of 252 children sedated in the hospital in November 2005, 153 cases (60.7%) did not have any sort of monitoring on them (this includes 114 cases from EEG lab and 16 cases from the audiology lab). *Post procedure*, of the 252 cases 171 cases (67.9%) were not monitored for complications.

Among the cases monitored for complications, 16 children developed potentially life threatening complications (category A) and one child had a respiratory arrest. Of the 16 cases, 13 were reported during the procedure (10 cases of desaturation, 1 case of airway obstruction, 2 cases

of laryngospasm) and 3 after the procedure (1case of desaturation, 1 of bradycardia and 1 of airway obstruction). The incidence of potentially life threatening events during the procedure is as high as 13 in 99 cases and the incidence of such events after the procedure is as high as 3 in 81 cases. There is a possibility that the unmonitored cases have had an equal or higher incidence of adverse events considering that in some cases more than one sedative drug was used. If that is the case then the chances of having a calamity during procedural sedation in children is not far away.

One child from the EEG lab who had cleft palate and ventricular septal defect had a near respiratory arrest. Critical incident analyses of that event revealed that inadequate preprocedural evaluation, use of three drugs and over dosage of drugs were all contributory.

A proper *recovery* area with facilities for oxygen, suction and monitoring was observed only in the gastroscopy suite and in the pediatric surgery OPD. All other areas lack a recovery area. Ideally the child should be discharged from the sedating area by a responsible person after he/ she is fully awake, able to speak, sit, stand or drink if appropriate for age. A recheck on the vital signs before discharge is strongly recommended. In most areas this was not followed either due to alack of a protocol or discharge criteria, an increased patient load or inadequate recovery room facilities.

The information gained by auditing one month's practice of procedural sedation in children is limited. As the number (n=252) is small and monitoring is almost nonexistent in some areas, statistical significance is difficult to calculate. However, there appears to be an enormous clinical significance. After analyzing the present practice of procedural sedation and after having compared it with the international guidelines, we recommend few changes to the present system. These changes have been drafted based on the Indian standards and the institutional policies. These

are only guidelines and have to be amended based on the specific need of the situation.

Recommendations for “safe” sedation practices in children would include

1. Proper patient selection by a comprehensive preprocedural evaluation done by a doctor.
2. Obtaining informed consent from the parents after briefing them the risks and benefits of the procedure and sedation.
3. Monitoring the child during and after the procedure (till the child is fully conscious) for oxygen saturation, heart rate and the level of consciousness and recording of the vital signs every 5 minutes during the procedure and every 15 minutes after the procedure.
4. A proper recovery area with facility to provide oxygen and suction. The area should also have a pulsoximeter for each of the deeply sedated children.
5. To draft discharge criteria and to strictly adhere by it at the time of discharge.
6. Presence of a person who has advanced training in pediatric resuscitation where deep sedation is employed and that the assistant should have obtained training in Basic Life Support. Both the first and second person present at the time of sedation should have regular updates in life support training.
7. Propofol should be used only by person with advanced training in airway management. Midazolam provides faster recovery and renders the child street fit much earlier than diazepam. So we strongly recommend the use of midazolam as the hypnotic along with ketamine instead of diazepam.

8. We strongly recommend the use of flow sheets which are common to all the areas where sedation is given. Uniformity of a user friendly flow sheet will encourage documentation by the care givers.

   An ideal flow sheet should have the following details

   a. informed consent

   b. patient details-name, age, sex, weight and hospital number

   c. details of the preprocedure health evaluation done

   d. monitoring details

   e. a note on adverse events if any and

   f. the discharge criteria met at the time of discharge

CONCLUSION

Audit as defined by many authors implies a critical review of events. Clinical audit aims at detecting mismanagement and the “avoidability” of adverse outcomes of clinical management. In our audit, we detected varying degrees of mismanagement in each of the seven areas studied. The pitfalls both in terms of the “structure” and “process” of procedural sedation in children were pointed out to the concerned departments, with recommendations for changes in the existing policies so as to improve patient safety and outcome. Some of these recommendations are already being implemented as seen in the EEG lab which is now sedating children based on their weight. The use of largactil is also banned in the lab.

Thus clinical audit can be rightly considered an action-oriented research, aimed at putting findings into operation in order to correct mismanagement and to improve norms with a focus on avoidability issues

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APPENDICES

APPENDIX I

PROFORMA 1-STRUCTURE

PLACE :

Facilities available:

1. Source of oxygen -- wall supply/cylinder/ nil
2. Pediatric ambu bag
   Adult ambu bag
3. Face mask - sizes available 1 2 3 4 5
   Numbers
4. Oral airway- sizes available 1 2 3 4 5
   Numbers
5. Laryngoscope (working)-size of the blades 00 0 1 2 3
   Numbers
6. ET tubes –sizes available 3 3.5 4 4.5 5 5.5 6 6.5 7
   Numbers
7. LMA Sizes
   Numbers
7. Suction apparatus – wall suction /machine
8. Tipping table
9. IV canulae –sizes available 24G 22G 20G 18G 16G
   Numbers
10. Pulsoximeter
11. ECG leads & monitor
12. BP apparatus
13. NIBP cuff & monitor
14. Nursing staff
    Training in BLS –regular attendance/once attended/not trained
    Average patient turnover per day
15. Is recovery area available?
    If yes, Suction
    Oxygen
    Pulsoximeter Nursing staff

Is there a written protocol for sedation?

When was it written?

What drugs are used for sedation?

How much?

How is the dose decided?

Who decides?

Are the drug details documented?

Whether patient relative informed of the sedation?

When is the patient discharged?

What are the discharge criteria met?

PROFORMA 2-PROCESS

PAEDIATRIC SEDATION

Date: Place of procedure:

PATIENT INFORMATION

Name: Hosp. no Mrd no.

Weight: Firm/unit:

Diagnosis:

Procedure: Consent for Procedure: Y /N

Current medications: Sedation: Y /N

PRESEDATION HISTORY & ASSESSMENT

History: Fever

Respiratory tract infection

Asthma/resp. problems

Cardiac problems

Apnea/snoring

Personal/family h/o anesthetic problems

Others

Examination:

Facial anomalies

CVS:

RS:

PROCEDURE/PATIENT MONITORING

Trained in

Personnel present: Y/N BLS PALS

Physician/surgeon performing the procedure

Anesthetist

Nurse

Paramedical worker

Others

DRUGS USED:

	DOSE	TIME
1.TRICHLORYL		
2.ORAL DIAZEPAM		
3.KETAMINE		
4.ATROPINE		
5. OTHERS		

MONITORING:

TIME	PR	BP	RR	SpO2	LOC	RESPONSE TO STIMULUS	COMMENTS
0 min							
5 min							
10 min							
15 min							
30 min							
60 min							
2 hrs							
4 hrs							
6 hrs							
8 hrs							

LOC (level of consciousness)
A- Awake
C- Crying
L- Lethargic
S- Sleeping

Response to stimulus
V- verbal
T -tactile
P- painful
D- deep sedation

Is recovery area available? Y /N

If yes, facilities available in the recovery area:

Oxygen: Y /N
Suction: Y /N
Pulsoximetry: Y /N

POSTPROCEDURAL COMPLICATIONS

1. Desaturation

2. Apnea/respiratory problems

3. Airway obstruction

4. Bradycardia

5. Hemodynamic instability

6. Cardiac arrest

7. Nausea& vomiting

8. Others

POST SEDATION DISCHARGE CRITERIA MET

YES NO

1. Vital signs normal for age

2. Absence of respiratory distress

3. Necessity for supplemental O2

4. Nausea/vomiting

5. Awake &responding to command
(If appropriate for age)

6. Able to speak (if appropriate for age)

7. Able to sit, stand/walk with help:

8. Is the patient being sent to another area for sedation/procedure?

DISCHARGED BY: DESIGNATION:

TIME OF DISHARGE:

APPENDIX III

FREQUENCIES AND PERCENTAGES OF DEFICIENCIES

Consent for procedure

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NOT OBTAINED	73	29.0	29.0	29.0
	OBTAINED	179	71.0	71.0	100.0
	Total	252	100.0	100.0	

Cardiovascular system

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NOT EXAMINED	130	51.6	51.6	51.6
	NORMAL	119	47.2	47.2	98.8
	ABNORMAL	3	1.2	1.2	100.0
	Total	252	100.0	100.0	

Respiratory system

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not examined	130	51.6	51.6	51.6
	normal	120	47.6	47.6	99.2
	abnormal	2	.8	.8	100.0
	Total	252	100.0	100.0	

Physician trained in BLS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	163	64.7	64.7	64.7
	yes	89	35.3	35.3	100.0
	Total	252	100.0	100.0	

Physician trained IN PALS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	210	83.3	83.3	83.3
	yes	42	16.7	16.7	100.0
	Total	252	100.0	100.0	

Anesthetist

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	absent	197	78.2	78.2	78.2
	present	55	21.8	21.8	100.0
	Total	252	100.0	100.0	

Anesthetist trained in PALS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	185	73.4	73.4	73.4
	yes	10	4.0	4.0	77.4
	2	57	22.6	22.6	100.0
	Total	252	100.0	100.0	

Trichlofos

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not given	140	55.6	55.6	55.6
	less than 50 mg/kg	9	3.6	3.6	59.1
	51-75 mg/kg	28	11.1	11.1	70.2
	76-100 mg/kg	2	.8	.8	71.0
	not based on body weight	73	29.0	29.0	100.0
	Total	252	100.0	100.0	

APPENDIX IV

FREQUENCIES OF COMPLICATIONS

0 min saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	153	60.7	60.7	60.7
	less than 90%	3	1.2	1.2	61.9
	90-95%	2	.8	.8	62.7
	95-100%	94	37.3	37.3	100.0
	Total	252	100.0	100.0	

5 MIN saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	189	75.0	75.0	75.0
	less than 90%	1	.4	.4	75.4
	90-95%	2	.8	.8	76.2
	95-100%	60	23.8	23.8	100.0
	Total	252	100.0	100.0	

10 MIN saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	194	77.0	77.0	77.0
	95-100%	57	22.6	22.6	99.6
	4	1	.4	.4	100.0
	Total	252	100.0	100.0	

15 min saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	178	70.6	70.6	70.6
	90-95%	2	.8	.8	71.4
	95-100%	72	28.6	28.6	100.0
	Total	252	100.0	100.0	

30 MIN saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	206	81.7	81.7	81.7
	95-100%	46	18.3	18.3	100.0
	Total	252	100.0	100.0	

60 min saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	223	88.5	88.5	88.5
	95-100%	29	11.5	11.5	100.0
	Total	252	100.0	100.0	

2 hours saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	241	95.6	95.6	95.6
	95-100%	10	4.0	4.0	99.6
	4	1	.4	.4	100.0
	Total	252	100.0	100.0	

4 hours saturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not monitored	245	97.2	97.2	97.2
	95-100%	7	2.8	2.8	100.0
	Total	252	100.0	100.0	

Post procedure desaturation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	1	1	.4	.4	68.3
	2	80	31.7	31.7	100.0
	Total	252	100.0	100.0	

Apnea/respiratory problems

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	1	2	.8	.8	68.7
	2	79	31.3	31.3	100.0
	Total	252	100.0	100.0	

Airway obstruction

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	1	1	.4	.4	68.3
	2	80	31.7	31.7	100.0
	Total	252	100.0	100.0	

Bradycardia

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	1	2	.8	.8	68.7
	2	79	31.3	31.3	100.0
	Total	252	100.0	100.0	

Hemodynamic instability

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	2	81	32.1	32.1	100.0
	Total	252	100.0	100.0	

Cardiac arrest

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	2	81	32.1	32.1	100.0
	Total	252	100.0	100.0	

Nausea and vomiting

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	171	67.9	67.9	67.9
	1	2	.8	.8	68.7
	2	79	31.3	31.3	100.0
	Total	252	100.0	100.0	